EMD Serono and Emmaus Medical Announce Promotional Rights Agreement for Zorbtive® in the United States

EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt Germany, and Emmaus Medical, Inc. announced today that they have entered into a promotional rights agreement of EMD Serono's product Zorbtive (somatropin (rDNA origin) for injection) for the treatment of short bowel syndrome in patients receiving specialized nutritional support. EMD Serono has granted Emmaus Medical the exclusive rights to detail and promote Zorbtive in the United States, but has retained all other rights.

"We are excited about the agreement with Emmaus Medical, which demonstrates our strong business development imperative to secure the right partnerships that ensure patients have access to high quality, novel medicines we have developed," said Bharat Tewarie, MD, Vice President, Head of Business Development, EMD Serono, Inc.

Zorbtive is the first medication approved by the Food and Drug Administration for the treatment of short bowel syndrome (SBS).

used in conjunction with Zorbtive.

"We are confident that our expertise in understanding patients and prescribers gives us the opportunity to bring an outstanding product to people living with a rare condition, such as short bowel syndrome," said Yutaka Niihara, MD, President and CEO, Emmaus Medical. "We are pleased to work with EMD Serono to make this possible."

Under the promotional rights agreement, Emmaus Medical will build awareness and education among physicians and healthcare professionals experienced in the SBS diagnosis and management about Zorbtive used in conjunction with NutreStore and a specialized diet tailored to meet a patient's specific needs as a treatment therapy for people living with short bowel syndrome who are receiving specialized nutritional support. This deal is an example of EMD Serono's business imperative to develop collaborations with companies such as Emmaus Medical that together are committed to improving the lives of people living with significant unmet medical needs.

Short bowel syndrome is a condition when two-thirds or more of a person's small intestine is removed or not functioning properly. The small intestine is an important part of a person's digestive system, absorbing almost 90% of the nutrients and fluids needed to sustain health and life. There are an estimated 15,000 to 20,000 people living with short bowel syndrome in the United States.

About EMD Serono, Inc.

EMD Serono, Inc, an affiliate of Merck KGaA Darmstadt, Germany, is a leader in the US biopharmaceutical arena, integrating cutting-edge science with unparalleled patient support systems to improve people's lives. The company has strong market positions in neurodegenerative diseases, with Rebif® (interferon beta-1a), as well as in endocrinology, with Saizen® (somatropin (rDNA origin) for injection), Serostim® (somatropin (rDNA origin) for injection) and Zorbtive™ (somatropin (rDNA origin) for injection). EMD Serono is a leader in fertility treatments, with Gonal-f® (follitropin alpha for injection), Luveris® (lutropin alpha for injection) and Ovidrel® Prefilled Syringe (choriogonadotropin alpha injection).

For more information, please visit www.emdserono.com.

About Emmaus Medical, Inc.

Medical launched its first product, NutreStore™ (L-glutamine powder for oral solution) in June 2008, and received exclusive rights to detail and promote Zorbtive™ (somatropin (rDNA origin) for injection) in December 2008. Emmaus Medical is currently conducting clinical trials to investigate the safety and efficacy of oral L-glutamine for sickle cell disease. Emmaus Medical received FDA orphan drug designation and fast track designation for the sickle cell project.

For more information, please visit www.emmausmedical.com and www.nutrestore.com.

Media Alert Contact: Renee Connolly 781-681-2340

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EMD Serono's Oral Investigational Treatment Cladribine Tablets for Multiple Sclerosis Significantly Reduced Relapse Rate in Two-Year Phase III Pivotal Trial

- **Two-year primary efficacy endpoint of CLARITY trial met: 58% relative reduction in annualized relapse rate in the low total dose treatment group and 55% in the high total dose treatment group**
- **Submission for registration of cladribine tablets planned for mid-2009**
- **Cladribine tablets are the first oral investigational multiple sclerosis treatment to complete a two-year pivotal study**

Rockland, Massachusetts, January 23, 2009 – EMD Serono, a division of Merck KGaA, Darmstadt, Germany, announced today that the CLARITY1 Phase III pivotal trial of its proprietary oral formulation of cladribine (cladribine tablets) met the two-year primary endpoint of clinical relapse rate reduction in patients with relapsing-remitting multiple sclerosis (MS).

The two cladribine tablet treatment groups of the study, assessing different dose regimens, demonstrated a statistically significant reduction in the annualized rate of relapses compared to

p<0.001). Patients from the higher total dose group experienced a 55% relative reduction in annualized relapse rates with respect to placebo (0.15 versus 0.33; p<0.001).

Overall, the frequencies of adverse events were low in the cladribine tablet treatment groups and were comparable to that observed in the placebo group. Lymphopenia, an expected event based on the presumed mechanism of action of cladribine, occurred more frequently in the cladribine tablet treatment groups. With the exception of lymphopenia, the most frequently reported adverse events in the three study groups were headaches and nasopharyngitis.

"We believe the CLARITY data mark an important milestone in the assessment of investigational oral treatments for multiple sclerosis and that cladribine tablets have the potential to make a real difference in the lives of patients," said Elmar Schnee, Member of the Executive Board Merck KGaA and Head of Pharmaceuticals. "Based on the successful completion of the CLARITY study, we plan to submit cladribine tablets for registration to the EMEA and to the FDA for mid-2009."

Secondary endpoints of the CLARITY study were also met, including reduction of lesion activity as measured by magnetic resonance imaging (MRI), proportion of subjects relapse-free and disability progression. Full study results will be submitted for presentation at an upcoming scientific meeting.

The CLARITY study was a two-year (96 weeks), randomized, double-blind, placebo-controlled, international trial. It enrolled 1,326 patients with relapsing-remitting MS according to the revised McDonald criteria2 . Study participants were randomized to one of three different treatment groups consisting of two different dose regimens of cladribine tablets or matching placebo tablets (1:1:1 ratio). Cladribine tablets were given in two or four treatment courses in the first year, with each course consisting of once daily administration for four to five consecutive days, which means study patients took cladribine tablets for only 8 to 20 days during the year. In the second year, two treatment courses were administered to all patient groups. The primary endpoint of the CLARITY study was the qualifying relapse rate at 96 weeks. Secondary endpoints included MRI endpoints3 , proportion of subjects relapsefree and disability progression at 96 weeks. Out of the 1,326 randomized patients, 90% of patients treated with cladribine tablets completed the study (92% in the lower total dose group and 89% in the higher total dose group) compared to 87% in the placebo group.

2 The McDonald criteria are diagnostic criteria for MS. In April 2001 an international panel in association with the National Multiple Sclerosis Society (NMSS) of America recommended revised diagnostic criteria for MS. They make use of advances in MRI imaging techniques and are intended to replace the Poser criteria. The new criteria facilitate the diagnosis of MS in patients who present with signs and symptoms suggestive of the disease. The McDonald criteria for the diagnosis of multiple sclerosis were revised in 2005 to simplify and speed diagnosis, while maintaining adequate sensitivity and specificity.

3 The exact correlation between MRI findings and the current or future clinical status of patients, including disability progression, is unknown.

About cladribine tablets

Merck Serono's proprietary oral formulation of cladribine (cladribine tablets) is currently being evaluated in Phase III as a treatment for patients with relapsing forms of multiple sclerosis (MS). Cladribine is a small molecule that may interfere with the behavior and the proliferation of certain white blood cells, particularly lymphocytes, which are thought to be involved in the pathological process of MS.

The clinical development program for cladribine tablets includes:

- The CLARITY (CLAdRIbine Tablets Treating MS OrallY) extension study: a two-year placebo-controlled extension of the CLARITY study, designed to provide data on the long-term safety and efficacy of extended administration of cladribine tablets for up to four years

- The ORACLE MS (ORAl CLadribine in Early MS) study: a two-year Phase III placebo-controlled trial designed to evaluate the efficacy and safety of cladribine tablets as a monotherapy in patients at risk of developing MS (patients who have experienced a first clinical event suggestive of MS). This trial was announced in September 2008.

- The ONWARD (Oral Cladribine Added ON To Rebif New Formulation in Patients With Active Relapsing Disease) study: a Phase II placebo-controlled trial designed primarily to evaluate the safety and tolerability of adding cladribine tablets treatment to patients with relapsing forms of MS, who have experienced breakthrough disease while on established interferon-beta therapy. This trial was announced in January 2007.

forms of multiple sclerosis.

About multiple sclerosis

Multiple sclerosis (MS) is a chronic, inflammatory condition of the nervous system and is the most common, non-traumatic, disabling neurological disease in young adults. The World Health Organization estimates that up to 2.5 million people suffer from MS worldwide. While symptoms can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common.

About EMD Serono

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For more information, please visit www.emdserono.com

About Merck KGaA

Merck is a global pharmaceutical and chemical company with total revenues of EUR 7.1 billion in 2007, a history that began in 1668, and a future shaped by 30,968 employees in 60 countries. Its success is characterized by innovations from entrepreneurial employees. Merck's operating activities come under the umbrella of Merck KGaA, in which the Merck family holds an approximately 70% interest and free shareholders own the remaining approximately 30%.

For more information, please visit www.merckserono.net or www.merck.de

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EMD Serono, Inc. Announces Expansion with Research Site in Cambridge, Massachusetts

- Supports US Drug Discovery Activities in Neurodegenerative Diseases

Rockland, Massachusetts -- EMD Serono, Inc. announced today that it will open a site in Cambridge, Massachusetts to support its growing Research function. The Cambridge laboratory space will accommodate EMD Serono's US drug discovery activities in neurodegenerative diseases such as multiple sclerosis (MS), which will augment the company's existing US research in oncology and fertility. EMD Serono expects to occupy the site with nearly 50 scientists across disciplines, including neurobiology, pharmacology and chemistry, to work at the location.

"This research expansion further supports EMD Serono's commitment to develop and deliver innovative therapies for patients in our areas of focus," said Fereydoun Firouz, President and CEO, EMD Serono, Inc. "EMD Serono is following our outlined strategy to broaden our research capabilities by expanding our footprint in the state of Massachusetts in close proximity to leading academic centers and qualified expertise that can be complimentary to our organization and add researchers that can grow with our team. I am proud to be delivering on our plans of

"EMD Serono's continued expansion in Massachusetts confirms the leadership's commitment to growing in the state and providing talented individuals with potential employment opportunities as they work to develop new treatment options for the many patients in need," said Robert Coughlin, President and CEO of Massachusetts Biotechnology Council. "This is an important announcement, during this time of economic pressure that gives some reassurance that leading biopharmaceutical companies such as EMD Serono have stability with hiring, expanding and investing plans still on track." In 2008, EMD Serono announced a planned expansion of its Billerica laboratory to create a center of excellence in discovery, which is scheduled for completion in 2010. The Cambridge satellite laboratory, which will be approximately 18,000 square feet in size, will address the company's immediate need to secure necessary laboratory space for its additional scientists as a result of accelerated employee growth.

EMD Serono completed the first Phase III trial of an oral multiple sclerosis drug, cladribine, which is targeted for registration filing later this year. With these additional capabilities the company plans to focus research and development efforts towards Parkinson's disease, and other neurodegenerative diseases.

About EMD Serono, Inc.

EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, is a leader in the US biopharmaceutical arena, integrating cutting-edge science with unparalleled patient support systems to improve people's lives. The company has strong market positions in neurodegenerative diseases, with Rebif® (interferon beta-1a), as well as in endocrinology, with Saizen® (somatropin (rDNA origin) for injection) and Serostim® (somatropin (rDNA origin) for injection). EMD Serono is a leader in fertility treatments, with Gonal-f® (follitropin alfa for injection), Luveris® (lutropin alfa for injection) and Ovidrel® Prefilled Syringe (choriogonadotropin alpha injection). With a clear focus on the patient and a leadership presence in the biopharmaceutical industry, EMD Serono's US footprint continues to grow, with more than 1000 employees around the country and fully integrated commercial, clinical and research operations in the company's home state of Massachusetts.

For more information, please visit www.emdserono.com

Two-Year Phase III Data Presented at AAN 61st Annual Meeting Show Positive Outcome of Cladribine Tablets in Patients with Multiple Sclerosis

- **Primary endpoint met with a significant reduction in relapse rate**
- **Secondary endpoints met including MRI measures, proportion of patients relapse-free and disability progression**
- **Submission for registration of Cladribine Tablets planned for mid-2009**

Rockland, Massachusetts, Seattle, WA, United States, April 29/30, 2009 – EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, announced today detailed results of the twoyear (96-week) placebo-controlled CLARITY1 Phase III trial using Cladribine Tablets (Merck Serono's proprietary investigational oral formulation of cladribine) to treat patients with relapsing-remitting multiple sclerosis (MS). The results of the pivotal trial show that annual short-course treatment with Cladribine Tablets led to a significant reduction in the rate of clinical relapses, disability progression and brain lesions, as well as a significant increase in the proportion of patients who remained relapse-free. The data were presented today for the first time, as a late-

"All primary and secondary endpoints of the CLARITY study were statistically significant and demonstrate that annual short-course treatment with Cladribine Tablets in this study was effective across multiple important clinical and MRI efficacy measures," said Dr. Gavin Giovannoni, principal investigator of the study, Institute of Cell and Molecular Science, Barts and The London School of Medicine and Dentistry, London, United Kingdom.

"We are very pleased with the successful outcome of the CLARITY study," said Elmar Schnee, Member of the Executive Board Merck KGaA and Head of Pharmaceuticals. "This is an exciting development in multiple sclerosis clinical research, and represents an important step towards delivering an oral therapy to people living with this condition."

The results from both Cladribine Tablets treatment groups in the study demonstrated a statistically significant reduction in the annualized rate of relapses compared to placebo (primary endpoint). Patients treated with the low-dose regimen of Cladribine Tablets experienced a 58% relative reduction in annualized relapse rates with respect to placebo (0.14 versus 0.33 for the placebo group; $p<0.001$). Patients in the high-dose regimen group experienced a 55% relative reduction in annualized relapse rates with respect to placebo (0.15 versus 0.33; $p<0.001$).

The proportion of patients who remained relapse-free (one secondary endpoint of the trial) was significantly higher in the Cladribine Tablets treatment groups than in the placebo group. Over the two-year period of the study, 80% of the patients treated with the low dose regimen of Cladribine Tablets and 79% of the patients treated with the high-dose regimen experienced no clinical relapse, compared with 61% of the patients from the placebo group ($p<0.001$ for both dose regimens). Therefore, the relative risk to relapse in patients treated with Cladribine Tablets was approximately half of that seen in patients on placebo.

Treatment with Cladribine Tablets led to a more than 30% reduction in the risk of disability progression (another secondary endpoint) relative to placebo over the two-year period of the study (low-dose regimen: hazard ratio=0.67; $p=0.018$ – high-dose regimen: hazard ratio=0.69; $p=0.026$). Progression of disability was measured by a 1-point or greater increase in the Expanded Disability Status Scale (EDSS) sustained for at least three months (or at least a 1.5 point increase if baseline EDSS was 0; or 0.5 point increase if baseline EDSS was 5.0 and above).

shown and were consistent with clinical outcomes. Over the two year period of the study, both dose regimens of Cladribine Tablets demonstrated a statistically significant reduction of at least 70% in the mean number of active T1 gadolinium-enhanced lesions per subject per scan, the mean number of active T2 lesions per subject per scan, as well as the mean number of combined unique lesions per subject per scan, compared to placebo (reductions ranging from 73% to 88% depending on MRI measure and dose group; $p<0.001$ for each of these MRI measures and for both dose regimens).

Overall, the frequencies of adverse events by MedDRA System Organ Class in both cladribine treatment groups were comparable to those observed in the placebo group. The most commonly reported adverse events were headaches, nasopharyngitis, upper respiratory tract infections and nausea. Lymphopenia, an expected event based on the presumed mechanism of action of cladribine, occurred more frequently in the Cladribine Tablets treatment groups (low-dose regimen: 22%; high-dose regimen: 31%; placebo: 2%).

The overall rate and incidence of infections in patients treated with Cladribine Tablets and placebo were similar. Herpes zoster infections were reported in 2.3% of patients treated with Cladribine Tablets. These herpes infections were localized to the skin and responded appropriately to treatment.

In patients treated with Cladribine Tablets, four malignancies were reported during the study (cervical stage 0, melanoma, ovarian and pancreatic), and a case of choriocarcinoma was reported at week 14 of gestation in a cladribine-treated patient who became pregnant 6 months after completion of the study. Observed malignancies were isolated cases across different organ systems. The current ongoing clinical studies with Cladribine Tablets will provide data on a larger patient population and a longer duration of treatment to collect more conclusive information on this safety aspect.

EMD Serono plans to submit Cladribine Tablets for registration to the US Food and Drug Administration (FDA) in mid-2009.

1 CLARITY: CLAdRIbine Tablets Treating MS OrallY

international trial. It randomized 1,326 patients with relapsing-remitting MS according to the revised McDonald criteria2 . Study participants were randomized to one of three different treatment groups consisting of two different dose regimens of Cladribine Tablets or matching placebo tablets (1:1:1 ratio). Cladribine Tablets were given in two or four treatment courses in the first year, with each course consisting of once daily administration for four to five consecutive days, which means study patients took Cladribine Tablets for 8 to 20 days during the year. In the second year, two treatment courses were administered to all patient groups. The primary endpoint of the CLARITY study was the qualifying relapse rate at 96 weeks. Secondary endpoints included MRI endpoints, proportion of subjects qualifying relapse-free and disability progression at 96 weeks. Out of the 1,326 randomized patients, 90% of patients treated with Cladribine Tablets completed the study (92% in the lower total dose group and 89% in the higher total dose group) compared to 87% in the placebo group.

About Cladribine Tablets

EMD Serono's proprietary oral formulation of cladribine (Cladribine Tablets) is currently being evaluated in Phase III as a treatment for patients with relapsing forms of multiple sclerosis (MS). Cladribine is a small molecule that may interfere with the behavior and the proliferation of certain white blood cells, particularly lymphocytes, which are thought to be involved in the pathological process of MS. The clinical development program for cladribine tablets includes:

- The CLARITY (CLAdRIbine Tablets Treating MS OrallY) extension study: a two-year placebo-controlled extension of the CLARITY study, designed to provide data on the long-term safety and efficacy of extended administration of Cladribine Tablets for up to four years

- The ORACLE MS (ORAl CLadribine in Early MS) study: a two-year Phase III placebo-controlled trial designed to evaluate the efficacy and safety of Cladribine Tablets as a monotherapy in patients at risk of developing MS (patients who have experienced a first clinical event suggestive of MS). This trial was announced in September 2008.

- The ONWARD (Oral Cladribine Added ON To Rebif New Formulation in Patients With Active Relapsing Disease) study: a Phase II placebo-controlled trial designed primarily to evaluate the safety and tolerability of adding Cladribine Tablets treatment to patients with relapsing forms of MS, who have experienced breakthrough disease while on established interferon-beta therapy.

subset of patients with relapsing forms of multiple sclerosis.

About multiple sclerosis

Multiple sclerosis (MS) is a chronic, inflammatory condition of the central nervous system and is the most common, non-traumatic, disabling neurological disease in young adults. It is estimated that more than two million people have MS worldwide. While symptoms can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common.

About EMD Serono, Inc.

EMD Serono is the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada - a leading science and technology company - focused exclusively on specialty care. For more than 40 years, the business has integrated cutting-edge science, innovative products and industry-leading patient support and access programs. EMD Serono has deep expertise in neurology, fertility and endocrinology, as well as a robust pipeline of potential therapies in oncology, immuno-oncology and immunology as R&D focus areas. Today, the business has 1,300 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts. www.emdserono.com

About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of €15.0 billion in 66 countries.

Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, holds the global rights to the "Merck"

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EMD Serono, Inc. and Fast Forward, LLC Commit $3 Million in 2009 To Early Stage Drug Development For Multiple Sclerosis

- **Proposals sought from academic institutions and seed-to-early stage companies developing novel therapeutic approaches to prevent, treat or reverse nervous system damage in multiple sclerosis**

Rockland, MA/New York, NY, May 1, 2009 – EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt Germany, and Fast Forward, LLC, a wholly-owned subsidiary of the National Multiple Sclerosis Society, today announced a commitment of $3 million in 2009 to support innovative early-stage projects directed towards the development of therapies to prevent treat, or reverse nervous system damage in multiple sclerosis (MS). This is the first 'Request for Proposals' (RFP) issued under the auspices of a multi-year collaboration between Fast Forward and Merck KGaA to accelerate innovation and commercial development of MS therapies. Merck KGaA will provide up to $19 million in total funding.

"Our goal is to accelerate the discovery and commercial development of innovative MS therapies and bring these new and improved treatments to the people with MS who need them," reported Dr. Timothy Coetzee, President of Fast Forward. "A unique feature of this RFP is

This RFP will complement Fast Forward's ongoing research funding programs wherein it has established a strong presence in early-stage drug discovery for MS. Fast Forward will continue to provide critical resources for underfunded academic institutions and seed-to-early-stage companies engaged in innovative research in support of its commitment to end multiple sclerosis.

"EMD Serono is pleased to join forces with Fast Forward to drive the development of a new generation of MS therapies," said Steve Arkinstall, Vice President, US Research, EMD Serono, Inc. "By providing university researchers and early-stage companies with an opportunity for follow-on funding and continued collaboration, we can close the gap between the laboratory discoveries and life changing therapies for people with MS."

Fast Forward is seeking proposals for funding through the Accelerating Innovation and the Accelerating Commercial Development programs. The Accelerating Innovation program is open to academic institutions, non-profit research organizations, and seedstage for-profit commercial organizations. The Accelerating Commercial Development program is open to early-stage for-profit commercial organizations that have achieved Series A or comparable investment funding.

Priority research areas for this RFP include:

• modulation of innate and/or adaptive immunity to promote central nervous system (CNS) neuroprotection and/or repair;

• molecular strategies for direct CNS neuroprotection;

• molecular approaches for CNS repair and remyelination;

• regenerative cell therapies and related platform technologies.

The commitment of $3 million in 2009 is comprised of up to $250,000 in funding available for one year to each awardee selected through the Accelerating Innovation program and up to $500,000 in funding available for one year to each awardee selected through the Accelerating Commercial Development program.

RFPs are available on Fast Forward's web site, www.fast.forward.org along with eligibility criteria for both programs and instructions for submission of a preliminary proposal.

Preliminary proposals are required of all applicants and must be submitted online by July 28, 2009. Preliminary proposals will be reviewed by the Fast Forward's staff and a panel of experts drawn from Fast Forward's Scientific and Business Advisory Committee. Applicants whose preliminary proposals are determined to meet the review criteria will be invited to submit full proposals which will be due in late October, 2009. Funding is anticipated by December 2009. All funding disbursements will be managed and approved by the Fast Forward Board of Directors.

About multiple sclerosis

Multiple sclerosis (MS) is a chronic, inflammatory condition of the central nervous system and is the most common, non-traumatic, disabling neurological disease in young adults. It is estimated that more than 2 million people have MS worldwide. While symptoms can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common.

About Fast Forward, LLC

Fast Forward, LLC is a nonprofit organization established by the National Multiple Sclerosis Society in order to accelerate the development of treatments for MS. Fast Forward will accomplish its mission by connecting university-based MS research with private-sector drug development and by funding small biotechnology/pharmaceutical companies to develop innovative new MS therapies and repurpose FDAapproved drugs as new treatments for MS. For more information visit www.fastforward.org

About the National Multiple Sclerosis Society

The National MS Society addresses the challenges of each person affected by MS through funding cutting-edge research, driving change through advocacy, facilitating professional education, collaborating with MS organizations around the world, and providing programs and

over $136 million to programs that enhanced more than one million lives. The Society also invested nearly $50 million to support 440 research projects around the world. The Society is dedicated to achieving a world free of MS. Join the movement at www.nationalMSsociety.org.

About EMD Serono

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For more information, please visit www.merckserono.com or www.merck.de

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MULTIPLE SCLEROSIS – WHAT ARE PEOPLE WITH MS AND THEIR HEALTH CARE PROVIDERS REALLY THINKING?

EXPLORE MORE

- **New national survey reveals insights on treatment of disease, psychosocial burden, and delays in starting treatment**

Rockland, MA/New York, NY, May 27, 2009 – The National Multiple Sclerosis (MS) Society, in collaboration with EMD Serono, today released findings from a nationwide GfK Roper survey, "MS Viewpoints: Understanding the Outlook on Emerging Therapies" in conjunction with the first-ever World MS Day. The MS Viewpoints survey compared the perspectives of neurologists, MS nurses and other healthcare professionals (HCPs)* and people living with MS on treatments, psychosocial burdens of the disease, and delays in starting treatment. Results from the survey uncovered that people newly diagnosed with MS often delay starting treatment, citing fear or anxiety about current treatment options as a key reason.

"At the National MS Society, we stress the importance of early treatment. It's critical for physicians and people living with MS to sit down early and have a candid conversation a[illegible]n individual's concerns, fears and options for treatment," said Dr. Nicholas LaRocca, vice

on people living with the disease starting at diagnosis."

Results from the survey revealed that nearly 20% of people living with MS reported delaying the start of treatment for a variety of reasons, including fear or anxiety over treatment. Differences emerged between physicians and people living with MS about how much this fear affects their lives. In the survey, the majority of physicians, and MS nurses and other HCPs reported that anxiety around treatment impacts people living with MS "a great deal" or "somewhat" compared to less than half of those living with the disease who expressed such views.

*Nursing and other HCPs survey participants included: registered nurses, certified medical assistants, licensed practical nurses, nurse practitioners, physicians' assistants and certified nurse specialists.

"Patient and physician dialogue has come a long way in recent years, but there is still work to be done," said Harold Moses Jr., MD, assistant professor of Neurology at Vanderbilt University. "As new therapies are approved and enter the market, we expect to see more discussion about whether these options are right for patients. In fact, the entire patient/physician dialogue may start to shift."

The MS Viewpoints survey uncovered that while individuals currently on treatment report being generally satisfied with their treatment, nearly one-third (33%) of people living with MS reported that their current MS treatment interferes with their quality of life and daily activities such as work/career, exercise routine and sleeping habits, topics that are more likely to be discussed by their MS nurse or other HCP than by their physician.

"The dialogue between a person living with MS and a nurse or other healthcare provider is important because it often focuses on the impact of MS on day-to-day activities," said Amy Perrin-Ross, APN, MSN, CNRN, MSCN, neuroscience program coordinator, Loyola University Chicago, and president of the International Organization of Multiple Sclerosis Nurses (IOMSN). "Perhaps this is why the survey showed that nurses and other HCPs were more likely than physicians to believe people with MS who initially delayed starting their prescribed MS therapy would have instead started therapy more quickly if an oral medication had been available."

About the Survey

relapsing MS. Interviews focused on understanding and comparing views of the current treatment landscape and the potential impact of emerging therapies, and also explored some of the psycho-social barriers that people living with MS face on a daily basis.

The survey was conducted via phone in the United States (US) by GfK Roper on behalf of the National MS Society in collaboration with EMD Serono between November 2008 and February 2009. The survey looked at neurologists (n=250), MS nurses and other HCPs (n=250) and people with relapsing MS (n=250). Following their survey, physicians were asked to recruit people with MS. Survey length averaged 19 minutes for neurologists and nurses and other HCPs, and 24 minutes for people living with MS. Statistical testing was done at a 95% confidence interval. A full methodology is available upon request.

About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic, progressive disease of the central nervous system (CNS) that affects approximately 400,000 Americans and as many as 2.1 million individuals worldwide. While symptoms can vary, the most common symptoms of MS include blurred vision, fatigue, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common.

About the National MS Society

The National MS Society addresses the challenges of each person affected by MS through funding cutting-edge research, driving change through advocacy, facilitating professional education, collaborating with MS organizations around the world, and providing programs and services designed to help people with MS and their families move their lives forward. In 2008 alone, through the national office and its 500-state network of chapters, the Society devoted over $136 million to programs that enhanced more than one million lives. The Society also invested nearly $50 million to support 440 research projects around the world. The Society is dedicated to achieving a world free of MS. Join the movement at: www.nationalmssociety.org.

About World MS Day

The first World MS Day will be observed on Wednesday, May 27, 2009 and on the last Wednesday of every May in the future. World MS Day has been established to raise awa of MS and the importance of the global MS movement, encourage enhanced international

Day. Register to be part of the global movement by visiting www.worldmsday.org, and make your voice heard in your local community by visiting www.nationalMSsociety.org.

About EMD Serono

EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, is a leader in the US biopharmaceutical arena, integrating cutting-edge science with unparalleled patient support systems to improve people's lives. The company has strong market positions in neurodegenerative diseases, with Rebif® (interferon beta-1a), as well as in endocrinology, with Saizen® (somatropin (rDNA origin) for injection), Serostim® (somatropin (rDNA origin) for injection) and Zorbtive™ (somatropin (rDNA origin) for injection). EMD Serono is a leader in fertility treatments, with Gonal-f® (follitropin alpha for injection), Luveris® (lutropin alfa for injection) and Ovidrel® Prefilled Syringe (choriogonadotropin alpha injection). With a clear focus on the patient and a leadership presence in the biopharmaceutical industry, EMD Serono's US footprint continues to grow, with more than 1000 employees around the country and fully integrated commercial, clinical and research operations in the company's home state of Massachusetts. For more information, please visit www.emdserono.com

About GfK Roper

GfK Roper Public Affairs & Media is a division of GfK Custom Research North America specializing in customized public opinion polling, media & communications research, and corporate reputation measurement – in the US and globally. In addition to delivering a broad range of customized research studies, GfK Roper Public Affairs & Media draws from GfK's syndicated consumer tracking services, GfK Roper Reports® US and GfK Roper Reports® Worldwide, which monitor consumer values, beliefs, attitudes and behaviors in the US and more than 25 other countries. Headquartered in New York, GfK Custom Research North America is part of the GfK Group. With home offices in Nuremburg, Germany, the GfK Group is the No. 4 market research organization worldwide. Its activities cover three business sectors: Custom Research, Retail and Technology, and Media. The Group has more than 115 companies covering 100 countries. For further information, visit: www.gfk.com.

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EMD Serono, Inc. and The University of Texas M. D. Anderson Cancer Center Announce Collaboration for Preclinical Research, Clinical Trials

Rockland, MA/Houston, TX, August 10, 2009 – EMD Serono, Inc. and The University of Texas M. D. Anderson Cancer Center today announced a strategic alliance designed to provide M. D. Anderson with early insight into potential cancer treatments and to accelerate EMD Serono's preclinical and early clinical research to ultimately bring new drugs to patients faster. The agreement is set for three years with the potential to renew the alliance. Both parties decided not to disclose financial details.

This non-exclusive strategic alliance will collaboratively draw on the expertise and resources of M. D. Anderson and EMD Serono to help design and conduct clinical trials for EMD Serono's oncology product candidates. M. D. Anderson is a leader in innovative approaches to oncology clinical trials.

oncology presence in the U.S.," said Dr. Bernhard Kirschbaum, Executive Vice President, Research & Development, Merck Serono. "We hope that through this alliance we are able to initiate important clinical trials faster and more efficiently to fully exploit our rich oncology pipeline. This is also a great opportunity to interact with scientists from M. D. Anderson to ultimately provide new treatment options for people living with cancer."

This collaboration brings together two leaders in the field of personalized medicine with a renewed commitment to the translational research that will ensure the identification and clinical development of biomarkers to tailor personalized cancer therapies to the needs of patients.

"The strategic alliance with EMD Serono allows us to collaborate with a leading biopharmaceutical organization to gain important, earlier insights into preclinical and clinical investigational compounds," said Dr. Robert Bast, M.D., Ph.D and Vice President for Translational Research at M. D. Anderson. "We believe there are many opportunities within this alliance to further expand both organizations' research initiatives and programs within oncology to bring more effective treatments to our patients."

This agreement underscores EMD Serono's commitment to partnering with academic and medical institutions in an effort to drive forward late stage research and early stage development. M. D. Anderson currently provides care for approximately 90,000 patients each year. In 2008, nearly 13,000 of its patients participated in clinical trials exploring novel treatments, the largest such program in the nation. EMD Serono is currently evaluating its oncology clinical pipeline, along with key investigators at M. D. Anderson, to determine which Phase I clinical trials will benefit from the strategic alliance, and expects, together, to begin patient enrollment for selected trials in 2009. About MD Anderson The University of Texas

M. D. Anderson Cancer Center in Houston ranks as one of the world's most respected centers focused on cancer patient care, research, education and prevention. M. D. Anderson is one of only 40 comprehensive cancer centers designated by the National Cancer Institute. For six of the past eight years, including 2009, M. D. Anderson has ranked No. 1 in cancer care in "America's Best Hospitals," a survey published annually in U.S. News & World Report.

About EMD Serono

systems to improve people's lives. The company has strong market positions in neurodegenerative diseases, with Rebif® (interferon beta-1a), as well as in endocrinology, with Saizen® (somatropin (rDNA origin) for injection) and Serostim® (somatropin (rDNA origin) for injection). EMD Serono is a leader in reproductive health, with Gonal-f® (follitropin alfa for injection), Luveris® (lutropin alfa for injection) and Ovidrel® Prefilled Syringe (choriogonadotropin alfa injection). With a clear focus on the patient and a leadership presence in the biopharmaceutical industry, EMD Serono's US footprint continues to grow, with more than 1000 employees around the country and fully integrated commercial, clinical and research operations in the company's home state of Massachusetts.

For more information, please visit www.emdserono.com

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EMD Serono Submits Application for Cladribine Tablets as a Potential Oral Short-Course Multiple Sclerosis Therapy in the United States

Rockland, Massachusetts, September 30, 2009 – EMD Serono, Inc. an affiliate of Merck KGaA, Darmstadt, Germany, announced today the submission of a New Drug Application (NDA) to the US Food and Drug Administration (FDA) for Cladribine Tablets, EMD Serono's proprietary investigational oral formulation of cladribine, as a therapy for reducing relapses in people with relapsing forms of multiple sclerosis (MS). Cladribine Tablets has the potential to be the first orally administered disease-modifying therapy available for people living with relapsing MS, as all disease-modifying therapies currently approved for the treatment of MS are parenteral therapies.

"As a leader in the area of neurodegenerative diseases, we continue to focus on making a positive difference in the lives of people living with MS, and their families," said Fereydoun Firouz, President and CEO of EMD Serono, Inc. "If approved, short-course therapy with Cladribine Tablets could transform the way people approach their treatment options, and meet

The NDA submission is supported by results from the CLARITY a study, a two-year, randomized, double-blind, placebo-controlled Phase III trial of Cladribine Tablets in people with relapsing-remitting MS. The NDA also shows that all primary and secondary endpoints of the CLARITY trial were met. The CLARITY data were presented at the 61st Annual Meeting of the American Academy of Neurology (AAN) in April 2009 and at other recent international scientific meetings.

a CLARITY: CLAdRIbine Tablets Treating MS OrallY

About the CLARITY study

The CLARITY study was a two-year (96-week), randomized, double-blind, placebo-controlled, international trial. It randomized 1,326 patients with relapsing-remitting MS according to the revised McDonald criteria. Study participants were randomized to one of three different treatment groups consisting of two different dose regimens of cladribine tablets or matching placebo tablets (1:1:1 ratio). Cladribine tablets were given in two or four treatment courses in the first year, with each course consisting of once daily administration for four to five consecutive days, which means study patients took Cladribine tablets for 8 to 20 days during the year. In the second year, two treatment courses were administered to all patient groups. The primary endpoint of the CLARITY study was the qualifying relapse rate at 96 weeks. Secondary endpoints included MRI endpoints, and proportion of subjects qualifying relapse-free and disability progression at 96 weeks. Out of the 1,326 randomized patients, 90% of patients treated with Cladribine tablets completed the study (92% in the lower total dose group and 89% in the higher total dose group) compared to 87% in the placebo group.

About Cladribine Tablets

EMD Serono’s oral formulation of cladribine (cladribine tablets) is currently being evaluated in Phase III as a treatment for patients with relapsing forms of multiple sclerosis (MS). Cladribine is a small molecule that may interfere with the behavior and the proliferation of certain white blood cells, particularly lymphocytes, which are thought to be involved in the pathological process of MS.

The clinical development program for cladribine tablets includes:

and efficacy of extended administration of cladribine tablets for up to four years.

- The ORACLE MS (ORAl CLadribine in Early MS) study: a two-year Phase III placebo-controlled trial designed to evaluate the efficacy and safety of cladribine tablets as a monotherapy in patients at risk of developing MS (patients who have experienced a first clinical event suggestive of MS). This trial was announced in September 2008.

- The ONWARD (Oral Cladribine Added ON To Interferon beta-1a in Patients With Active Relapsing Disease) study: a Phase II placebo-controlled trial designed primarily to evaluate the safety and tolerability of adding cladribine tablets treatment to patients with relapsing forms of MS, who have experienced breakthrough disease while on established interferon-beta therapy. This trial was announced in January 2007.

Cladribine tablets have been granted a fast track designation by the US Food and Drug Administration based on the need for an oral therapy in a subset of patients with relapsing forms of multiple sclerosis.

About multiple sclerosis

Multiple sclerosis (MS) is a chronic, inflammatory condition of the central nervous system and is the most common, non-traumatic, disabling neurological disease in young adults. It is estimated that more than 2.5 million people have MS worldwide. While symptoms can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common.

About EMD Serono, Inc.

EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, is a leader in the US biopharmaceutical arena, integrating cutting-edge science with unparalleled patient support systems to improve people's lives. The company has strong market positions in neurodegenerative diseases, with Rebif® (interferon beta-1a), as well as in endocrinology, with Saizen® (somatropin (rDNA origin) for injection) and Serostim® (somatropin (rDNA origin) for injection). EMD Serono is a leader in reproductive health, with Gonal-f® (follitropin alfa for injection), Luveris® (lutropin alfa for injection) and Ovidrel® Prefilled Syringe

than 1000 employees around the country and fully integrated commercial, clinical and research operations in the company's home state of Massachusetts.

For more information, please visit www.emdserono.com

About Merck KGaA

Merck KGaA is a global pharmaceutical and chemical company with total revenues of € 7.6 billion in 2008, a history that began in 1668, and a future shaped by 32,800 employees in 59 countries. Its success is characterized by innovations from entrepreneurial employees. Merck's operating activities come under the umbrella of Merck KGaA, in which the Merck family holds an approximately 70% interest and free shareholders own the remaining approximately 30%. In 1917 the U.S. subsidiary Merck & Co. was expropriated and has been an independent company ever since.

For more information, please visit www.merckserono.com or www.merck.de

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